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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,924	10/31/2000	Hiroyoshi Hidaka	198323US0PCT	6890

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EXAMINER
TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
1639	18

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/647,924	Applicant(s) HIDAKA ET AL.	
	Examiner My-Chau T. Tran	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3 and 5-16* is/are pending in the application.

4a) Of the above claim(s) *14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,5-13,15 and 16* is/are rejected.

7)☒ Claim(s) *3,6,11 and 12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Note: The examiner for your application in the PTO has changed. However, the Group and/or Art Unit location of your application in the PTO is remained the same, which is Group Art Unit 1639.

1. Applicant's amendment filed 6/30/03 in Paper No. 17 is acknowledged and entered. Claims 2 and 4 are canceled by the amendment. Claims 5, 6, 11, and 12 are amended by the amendment. Claims 15-16 are added by the amendment.

2. Claims 3, and 5-16 are pending.

Election/Restrictions

3. Claim 14 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species (e.g. elected species of chemical cross-linker is glutaraldehyde), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11 and 13.

Withdrawn Rejections

4. The previous rejections 35 USC 112, second paragraph, for claims 2-13 have been withdrawn in view of applicant's amendments of claim 5, and the cancellation of claims 2 and 4.

5. The previous rejections under 35 USC 102(b) as being anticipated by Sparks et al. (WO 96/31625 (October 1996)) for claims 2-13 have been withdrawn in view of applicant's amendments of claim 5, and the cancellation of claims 2 and 4.

6. The previous rejections under 35 USC 103(a) as being obvious over Sparks et al. (WO 96/31625 (October 1996)) and Hutchens et al. (US Patent 5,161,615 November 1992) for claims 2-12 have been withdrawn in view of applicant's amendments of claim 5, and the cancellation of claims 2 and 4.

7. Applicant's arguments with respect to the rejection under 35 USC 112, first paragraph (written description), for Claims 13-23 have been considered but are moot in view of the new ground(s) of rejection.

8. Claims 3, 5-13, and 15-16 are treated on the merit in this Office Action.

New Rejections

Claim Objections

9. Claims 3, 6 and 11-12 are objected to because of the following informalities:

Claim 3, which depends on claim 5, is separated by cancel claim 4. Claim 6, which depends on claim 15, is separated by a series of different dependent claims. Claims 11-12, which depend on claim 16, are separated by a series of different dependent claims.

A claim, which depends from a dependent claim, should not be separated by any claim, which does not also depend from said dependent claim. A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to

another preceding claim. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n).

Appropriate correction is required.

10. Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The limitation of claim 3, which is "wherein the cDNA expression library is contained in a phage vector", is synonymous with the limitation in claim 5 of method step (c) that is "the cDNA expression library contained within the probe-bound phage". Therefore, it is unclear how claim 3 further limit claim 5.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 3, 5-13, and 15-16 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. <u>This is a written description rejection.</u>

These claims encompass a broad genus of drug that are "non-protein and *per se* exhibits no antigenicity". For example, claim 5 outlines the method steps for in vitro detection of a gene encoding a drug-targeted protein of ***any*** drug that are "non-protein and *per se* exhibits no antigenicity" wherein the method steps comprise of (a) linking an antigenic substance to a drug via a chemical cross-linker to form a probe (b) screening for the gene encoding a protein targeted by the drug, wherein the protein is expressed from a cDNA expression library and (c) determining the gene sequence of the protein expressed from the cDNA expression library contained within the probe-bound phage. The scope of this claimed "in vitro detection" method includes an infinite number of drugs with an infinite number of structural variants (i.e., drugs such as small organic molecules, carbohydrates, sugar, steroids, and aspirin) wherein no distinguishing structural attributes are provided for the members of the "drug". Additionally, the interaction (e.g. functionality) of the drug with any protein would depend on the type of functional group(s) on the drug and the binding site structure of the protein. Therefore, the newly added limitation of step (a) of "wherein the drug is non-protein and *per se* exhibits no antigenicity" would not provide ***any*** guidance as to the structure of the drug other than that it exclude protein of the claimed genus of drug. The specification and claims do not place any limit on the number of atoms, the types of atoms, or the manner in which said atoms might be connected to form the compounds or mixture of compounds. Although the specification discloses one example of a drug that is known to have "excellent anticancer drug" that is use in this method of detection (see Specification, pages 6-10), the specification and claims do not provide ***any*** guidance as to what structural features ***all*** of these drug share. Consequently, it is not possible to determine *a priori* which drug would encompass because there is no common

structural attributes that can link together ***all*** of these potential drug i.e., there is no teaching that would allow a person of skill in the art to determine *a priori* ***all*** the different types of drug compounds that should be included in this genus from the only one examples provide by applicants.

The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify ***all*** of the members of the genus or even a substantial portion thereof, and because the genus is enormous and highly variant, listing of only just one example of an "anticancer" drug (see specification, example, page 6) is insufficient to teach the entire genus. Consequently, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe this enormous genus. Thus, applicant was not in possession of the claimed genus.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 3, 5, 7, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Gram et al. (*Proc. Natl. Acad. Sci. USA*, **1992**, 89:3576-3580).

Gram et al. disclose a method for *in vitro* detection of a gene encoding a drug-targeted protein (Abstract; pg. 3578, left col., line 19 to right col. line 4). The method discloses the phage displaying low affinity Fabs binding to a progesterone-bovine serum albumin conjugate were

isolated from the library (Abstract; pg. 3577, left col., lines 44-62). The drug-targeted protein comprise of progesterone-bovine serum albumin (drug-serum albumin). The phage is from a murine cell (mammal cell). The method of Gram et al. anticipates the presently claimed method.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on Increased Flex Schedule and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
September 23, 2003

PADMASHRI PONNALURI
PRIMARY EXAMINER